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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,391	06/25/2001	Jacoba Adriana De Ronde	1930-A-PCT	9219

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,391

Applicant(s)

DE RONDE ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>17May2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 17 May 2004, which includes a 1.132 Declaration of J. A. De Ronde, an inventor.
2. Applicant has cancelled claims 1-22, and new claims 23-43 have been added. Claims 23-43 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

6. The Office acknowledges receipt of Applicant's IDS filed 17 May 2004, a signed copy of which is returned with the action.

Specification

7. The Office acknowledges receipt of an Abstract for this case as required by 37 CFR 1.72(b)

Claim Rejections - 35 USC § 112

8. Claims 23-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the transformation method containing a polyether polymethyl siloxane copolymer surfactant; (See specification, Examples 1-4, pgs. 5-11),

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does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a

The nature of the invention. Applicant's invention is a method of transforming a germinating plant seed that is susceptible to transformation with *Agrobacterium*, said method including (a) providing an *Agrobacterium* strain capable of transforming the germinating plant seed with a DNA of interest, (b) providing a wetting agent or surfactant that facilitates or enhances penetration and transformation of the germinating plant seed by the *Agrobacterium* strain, and (c) contacting the germinating plant seed with the wetting agent or surfactant and the *Agrobacterium* with the DNA of interest under conditions effective to cause cells of the plant germinating seed to be transformed with the DNA of interest to form a transformed plant seed, said conditions including a vacuum infiltration of the germinating plant seed while the germinating plant seed is contacting the wetting agent or surfactant and the *Agrobacterium*, and optionally a subsequent incubation of the germinating plant seed with the wetting agent or surfactant and the *Agrobacterium*, where the wetting agent or surfactant is a non-oil based wetting agent or surfactant, or comprises polyether polymethyl siloxane copolymer, where the plant seed is a dicot, or is from the Leguminosae family, or is a soybean seed or a lupine seed,

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The breadth of the claims. The claims are drawn broadly to a method of genetically modifying germinating seeds of any plant, by contacting them with any surfactant or wetting agent, in the presence of vacuum infiltration and of *Agrobacterium having any DNA of interest.*

Guidance: for the transformation method of preculturing *Agrobacterium* with acetosyringone (0.01 mg/ml) followed by concentrating the cells by centrifugation, followed by diluting the cells 1:4:: *Agrobacterium* : water containing 0.1% Break-Thru, a polyether polymethyl siloxane copolymer, sold in the trade as "Break-Thru; Germinating soybean seeds (2-5 days at 29 degrees) were added to the *Agrobacterium* + wetting agent suspension and vacuum infiltrated for 20 minutes under a pressure of 78 millitorr, and when the plants had developed a second set of leaves analyzed of expression (See specification, Examples 1-4, pgs. 5-11).

Re: The surfactant or wetting agent:

Applicant claims a method of genetically modifying plant seeds using any surfactant. Applicant teaches a method of modification using a specific surfactant, polyether polymethyl siloxane copolymer, sold in the trade as "Break-Thru". Surfactants are chemical agents able to decrease the surface tension of a liquid in which they are dissolved. Many surfactants are known, having many different chemistries, which include secondary alcohol ethoxylates, alkyl polyglucosides, alcohol alkoxylates, polyether sulfates and polyether-polymethylsiloxane-copolymers (see Dow Surfactants Products sheet, attached). Surfactants are known to be toxic to animals, plants, and bacteria, and evidenced by the product information supplied with the product label, (see

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attached Break-thru label). Therefore dosages and concentrations are critical in usage. It is unpredictable which specific surfactant, out of the many available, and at which dosage, will function as desired in the claimed invention. Without guidance from Applicant, one skilled in the art would need to do a myriad of experiments using different surfactants, dosages and various ratios of surfactant:Agrobacterium to find conditions which would function in the desired manner. Without further guidance, this would require excessive experimentation and impose undue burden on one skilled in the art.

Undue experimentation would be required Applicant claims a method of genetically modifying germinating plant seeds using Agrobacterium, vacuum infiltration, and any surfactant. The specific plant used (dicot, monocot, tree, algae or cactus) would have to be decided upon, followed by choosing the age and conditions for the germinating seed prior to treatment for transformation. Then experiments to determine which specific Agrobacterium (*A. tumefaciens* or *A. rhizogenes*) and what strain, with what T-DNA insert(s) of what DNA and genes of interest, including what selective markers, and if herbicide resistance markers are chose, to what herbicide would function as desired in transformation. Having the results of these experimentations, the conditions for transformation would have to be defined: Applicant teaches the use of Agrobacterium precultured with acetosyringone, in a liquid suspension together with Break Thru surfactant being added to the germinant seeds in vacuum infiltration conditions. Further experimentations would be required to determine which surfactant would function as desired: Surfactants are chemical agents able to decrease the surface tension of a liquid in which they are dissolved of which many surfactants are

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known, having many different chemistries, which include secondary alcohol ethoxylates, alkyl polyglucosides, alcohol alkoxylates, polyether sulfates and polyether-polymethylsiloxane-copolymers (see Dow Surfactants Products sheet, attached).

Furthermore, surfactants are known to be toxic to animals, plants, and bacteria, and evidenced by the product information supplied with the product label, (see attached Break-thru label). Therefore dosages and concentrations are critical in usage, especially where success requires proper biological function of the Agrobacterium to infect and transform the plant cells. It is unpredictable which specific surfactant, out of the many available, at what dosage and at which ratio of surfactant:Agrobacterium would function in the desired manner. Concurrently, the conditions for successful vacuum infiltration would have to be determined; vacuum treatment decreases the atmospheric conditions of the system treated, pulling air and water out of biological cells and tissues, potentially disrupting membranes and rupturing cell structures, so that to be successful, the vacuum pressure used, for what length of time and for how many treatment periods, would have to be determined. Applicant must provide sufficient guidance to address these issues. Without such guidance, the experimentation required would not be routine, but would be undue. This would impose a burden on the skilled artisan, without a reasonable expectation of success.

In view of the breadth of the claims (a method of genetically modifying any plant, any surfactant or wetting agent, any Agrobacterium, and any conditions of vacuum treatment), the nature of the invention, the unpredictability of the art, the lack the lack of

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guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

The Declaration of De Ronde

9. The Declaration of De Ronde has been thoroughly considered and is found not to be commensurate in scope with the scope of the claims.

De Ronde (Declaration p. 3) describes experiments detailed on pages 4-5 of the declaration involving vacuum infiltration of seed other than soybean, specifically lupine, wheat, canola and sunflower. The protocol used employed different conditions including different Agrobacterium T-DNA, different acetosyringone concentration, and resulted in "transformation success which varied between experiments, crops and cultivar" (p. 5). This is not clear if all, or only some, of the different plants tested were successfully transformed.

Claim Rejections - 35 USC § 102

10. Claims 23-31, 34-36 and 41- 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Richardson, et. al. (T-DNA tagging of the flowering time gene and improved gene transfer by in planta transformation of Arabidopsis, Australian J. Plant Physiol, May 1998, Vol 25, 125-130, Applicant's IDS).

Richardson. et. al. teach a method of transforming a germinating Arabidopsis thaliana seed that is susceptible to transformation with Agrobacterium, said method including (a) providing an Agrobacterium strain capable of transforming the germinating plant seed with a DNA of interest (p. 126, ¶ 4), (b) providing a wetting agent or

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surfactant (p. 126 ¶ 5) and (c) contacting the germinating *Arabidopsis thaliana* with the wetting agent or surfactant and the *Agrobacterium* with the DNA of interest under vacuum infiltration conditions for 5-40 minutes duration, while the germinating plant seed is contacting the wetting agent or surfactant and the *Agrobacterium* (p. 126, ¶ 6). Richardson. et. al. also teaches a subsequent incubation of the germinating *Arabidopsis thaliana* seed with the surfactant and the *Agrobacterium* (p. 126, ¶ 6, final 3 sentences). Richardson also teaches a transformed plant seed and a transgenic plant made by the claimed method.

Arabidopsis thaliana is a dicot plant. The germinating *Arabidopsis thaliana* seed is present in the flowering plant used for transformation; the flowering plant has flowering parts of many developmental stages and includes seed which has been pollinated and is germinating.

The *Agrobacterium* of Richardson. et. al. is *A. tumefaciens* GV3101/pMP90 containing the T-DNA bearing the bar-resistance selectable, a kanamycin-resistance gene and the GUS reporter gene marker, all containing appropriate regulatory regions for expression of these genes in transgenic plants

The surfactant of Richardson. et. al. is Stilwet L-77, a commercially available polyether polymethyl siloxane copolymer surfactant; surfactants are known to facilitate penetration of bacteria into plant cells.

Since the method of Richardson. et. al. uses the same method and method steps of transformation as the claimed invention, the seed of a plant and progeny

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thereof, produced by Richardson. et. al. is inherently the same as the claimed invention.

Accordingly Richardson. et. al. anticipates the claimed invention.

Remarks

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Transgenic Plants
22 July 2004




PHUONG T. BUI
PRIMARY EXAMINER 7/26/04